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DEC 22 2011

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,042,605 was filed on October 21, 2011, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Gore® Tag® CTAG Thoracic Endoprosthesis Device, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. We request the assistance of your Office to confirm that the Gore® Tag® CTAG Thoracic Endoprosthesis Device the subject of PMA P040043/S039, approved for Applicant, Gore Enterprise Holdings, Inc., on August 23, 2011, is the first commercial marketing or use of the product in light of the approval on March 23, 2005, of Gore Enterprise Holdings Inc.'s Gore® Tag® CTAG Thoracic Endoprosthesis Device the subject of PMA P040043 (see attached PMA approval letter http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040043a.pdf and label http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040043c.pdf, last accessed 12/15/2011)

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would not be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Gilbert R. Gabo
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